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APPLICANT: Fukui et al.

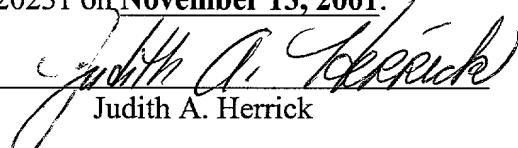
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FOR: MONOCLONAL ANTIBODY RECOGNIZING PHOSPHATIDYL-INOSITOL-3,4,5-TRIPHOSPHATE

CERTIFICATE OF MAILING

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Judith A. Herrick

Assistant Commissioner For Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Please amend the above-identified application filed herewith as follows:

IN THE CLAIMS:

Please cancel claims 1-17 without prejudice and add the following new claims:

18. An immunoassay method comprising the steps of:

- (a) reacting a monoclonal antibody specifically recognizing Phosphatidylinositol-3,4,5-triphosphate, or a variable region thereof, with phosphatidylinositol-3,4,5-3,4,5-triphosphate present in a sample; and,
- (b) detecting the binding based on an immunological reaction between said antibody, or said variable region thereof, and said triphosphate; wherein,

said monoclonal antibody binds to an antigenic determinant that contains an inositol group and a glycerol backbone in said phosphatidylinositol-3,4,5-triphosphate.

19. The immunoassay method of claim 15, wherein said monoclonal antibody does not cross-react with phosphatidylinositol-4,5-biphosphate.

20. An immunoassay method which comprises the steps of :

(a) reacting a monoclonal antibody specifically recognizing phosphatidylinositol-3,4,5-triphosphate, or a variable region thereof, with phosphatidylinositol-3,4,5-triphosphate present in a sample; and,

(b) detecting the binding based on an immunological reaction between said antibody, or said variable region, thereof, and the triphosphate; wherein,

said monoclonal antibody comprises an immunoglobulin, or variable region thereof, which recognizes phosphatidylinositol-3,4,5-triphosphate; wherein,

said immunoglobulin, or said variable region thereof, comprises an immunoglobulin heavy chain comprising:

- (i) CDR1 comprising the amino acid sequence of SEQ ID NO: 5;
- (ii) CDR2 comprising the amino acid sequence of SEQ ID NO: 6; and,
- (iii) CDR3 comprising the amino acid sequence of SEQ ID NO: 7.

21. The immunoassay method according to claim 19, wherein said immunoglobulin comprises an immunoglobulin light chain comprising:

- (i) CDR1 comprising the amino acid sequence of SEQ ID NO: 8;
- (ii) CDR2 comprising the amino acid sequence of SEQ ID NO: 9; and,
- (iii) CDR3 comprising the amino acid sequence of SEQ ID NO: 10.

22. The immunoassay method of claim 15, wherein said method comprises observing the degree to which the immunological reaction between the antibody, or a variable region

thereof, and an antigenic determinant recognized by said antibody, or said variable region thereof, is inhibited by phosphatidylinositol-3,4,5-triphosphate present in a sample.

23. An immunoassay kit for assaying Phosphatidylinositol-3,4,5-triphosphate, wherein said kit comprises a monoclonal antibody, or a variable region thereof, which:

- (a) specifically recognizes phosphatidylinositol-3,4,5-triphosphate; and;
- (b) binds to an antigenic determinant that contains an inositol group and a glycerol backbone in said phosphatidylinositol-3,4,5-triphosphate.

24. The immunoassay kit of claim 20, wherein said monoclonal antibody does not cross-react with Phosphatidylinositol-4,5-biphosphate.

25. An immunoassay kit for assaying phosphatidylinositol-3,4,5-triphosphate, wherein the kit comprises a monoclonal antibody specifically recognizing Phosphatidylinositol-3,4,5-triphosphate, or a variable region thereof, wherein said monoclonal antibody comprises an immunoglobulin, or variable region thereof, which recognizes Phosphatidylinositol-3,4,5-triphosphate, wherein said immunoglobulin, or variable region thereof, comprises an immunoglobulin heavy chain comprising:

- (i) CDR1 comprising the amino acid sequence of SEQ ID NO: 5;
- (ii) CDR2 comprising the amino acid sequence of SEQ ID NO: 6; and,
- (iii) CDR3 comprising the amino acid sequence of SEQ ID NO: 7.

26. The immunoassay kit of claim 22, wherein said immunoglobulin comprises an immunoglobulin light chain comprising:

- (i) CDR1 comprising the amino acid sequence of SEQ ID NO: 8;
- (ii) CDR2 comprising the amino acid sequence of SEQ ID NO: 9; and,
- (iii) CDR3 comprising the amino acid sequence of SEQ ID NO: 10.

REMARKS

Claims 1-17 have been canceled without prejudice and new claims 18-26 have been added. No new matter has been added by virtue of these amendments. Basis for the new claims can be found throughout the specification and the claims of the original application.

For example, new claims 18-22 are supported by Examples 1-4 (pages 15-22), and the disclosure on page 7, lines 19-28, to page 14, lines 1-23 of the specification.

New claims 23-26 are supported by Examples 1-4 (pages 15-22), and the disclosure on page 14, lines 24-29 to page 15, lines 1-8 of the specification.

Early examination and allowance of the application are respectfully requested.

Respectfully submitted,

DATE: 11-13-01



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1-17 were cancelled without prejudice.

New claims 18-26 were added:

18. (new) An immunoassay method comprising the steps of:

- (a) reacting a monoclonal antibody specifically recognizing phosphatidylinositol-3,4,5-triphosphate, or a variable region thereof, with phosphatidylinositol-3,4,5-3,4,5-triphosphate present in a sample; and,
- (b) detecting the binding based on an immunological reaction between said antibody, or said variable region thereof, and said triphosphate; wherein,
said monoclonal antibody binds to an antigenic determinant that contains an inositol group and a glycerol backbone in said phosphatidylinositol-3,4,5-triphosphate.

19. (new) The immunoassay method of claim 15, wherein said monoclonal antibody does not cross-react with phosphatidylinositol-4,5-biphosphate.

20. (new) An immunoassay method which comprises the steps of :

- (a) reacting a monoclonal antibody specifically recognizing phosphatidylinositol-3,4,5-triphosphate, or a variable region thereof, with phosphatidylinositol-3,4,5-triphosphate present in a sample; and,
- (b) detecting the binding based on an immunological reaction between said antibody, or said variable region, thereof, and the triphosphate; wherein,
said monoclonal antibody comprises an immunoglobulin, or variable region thereof, which recognizes phosphatidylinositol-3,4,5-triphosphate; wherein,
said immunoglobulin, or said variable region thereof, comprises an immunoglobulin heavy chain comprising:

- (i) CDR1 comprising the amino acid sequence of SEQ ID NO: 5;
- (ii) CDR2 comprising the amino acid sequence of SEQ ID NO: 6; and,
- (iii) CDR3 comprising the amino acid sequence of SEQ ID NO: 7.

21. (new) The immunoassay method according to claim 19, wherein said immunoglobulin comprises an immunoglobulin light chain comprising:

- (i) CDR1 comprising the amino acid sequence of SEQ ID NO: 8;
- (ii) CDR2 comprising the amino acid sequence of SEQ ID NO: 9; and,
- (iii) CDR3 comprising the amino acid sequence of SEQ ID NO: 10.

22. (new) The immunoassay method of claim 15, wherein said method comprises observing the degree to which the immunological reaction between the antibody, or a variable region thereof, and an antigenic determinant recognized by said antibody, or said variable region thereof, is inhibited by phosphatidylinositol-3,4,5-triphosphate present in a sample.

23. (new) An immunoassay kit for assaying Phosphatidylinositol-3,4,5-triphosphate, wherein said kit comprises a monoclonal antibody, or a variable region thereof, which:

- (a) specifically recognizes phosphatidylinositol-3,4,5-triphosphate; and;
- (b) binds to an antigenic determinant that contains an inositol group and a glycerol backbone in said phosphatidylinositol-3,4,5-triphosphate.

24. (new) The immunoassay kit of claim 20, wherein said monoclonal antibody does not cross-react with Phosphatidylinositol-4,5-biphosphate.

25. (new) An immunoassay kit for assaying phosphatidylinositol-3,4,5-triphosphate, wherein the kit comprises a monoclonal antibody specifically recognizing Phosphatidylinositol-3,4,5-triphosphate, or a variable region thereof, wherein said monoclonal antibody comprises an immunoglobulin, or variable region thereof, which recognizes Phosphatidylinositol-3,4,5-

triposphate, wherein said immunoglobulin, or variable region thereof, comprises an immunoglobulin heavy chain comprising:

- (i) CDR1 comprising the amino acid sequence of SEQ ID NO: 5;
- (ii) CDR2 comprising the amino acid sequence of SEQ ID NO: 6; and,
- (iii) CDR3 comprising the amino acid sequence of SEQ ID NO: 7.

26. (new) The immunoassay kit of claim 22, wherein said immunoglobulin comprises an immunoglobulin light chain comprising:

- (i) CDR1 comprising the amino acid sequence of SEQ ID NO: 8;
- (ii) CDR2 comprising the amino acid sequence of SEQ ID NO: 9; and,
- (iii) CDR3 comprising the amino acid sequence of SEQ ID NO: 10.